IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE, Plaintiff, v. MCNEIL-PPC, INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC.; JOHNSON & JOHNSON, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, Defendants.	CIVIL ACTION NO. 07-0348 Judge: Jan E. DuBois

DEFENDANTS' PRETRIAL MEMORANDUM

Defendants, McNEIL-PPC, Inc., McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. formerly known as and also sued as McNeil Consumer & Specialty Pharmaceuticals, a division of McNeil-PPC, Inc., Johnson & Johnson, and Johnson & Johnson Pharmaceutical Research and Development, LLC, in accordance with Local Rule 16.1 (c) and the Court's Pretrial Procedure for Civil Cases state as follows:

I. BRIEF STATEMENT OF NATURE OF THE ACTION AND THE BASIS ON WHICH JURISDICTION OF THE COURT IS INVOKED

This case involves claims for negligent failure-to-warn and strict liability failure-to-warn for alleged injuries and damages arising from Plaintiff's use of over-the-counter Children's Motrin in May and June, 1996. Plaintiff claims Children's Motrin caused her to develop *two* rare, poorly understood conditions known as Stevens-Johnson syndrome ("SJS") and Vanishing Bile Duct Syndrome ("VBDS"). The active ingredient in Children's Motrin is ibuprofen. Plaintiff seeks to recover punitive damages.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. manufactures and markets Children's Motrin. McNEIL-PPC, Inc. is an indirect subsidiary of Johnson & Johnson. Johnson & Johnson Pharmaceutical Research & Development, L.L.C. is also an indirect subsidiary of Johnson & Johnson.

The jurisdiction of the Court is invoked under 28 U.S.C. § 1332 based on diversity of citizenship between Plaintiff and Defendants and an amount in controversy exceeding $75,000.

II. DEFENDANTS' COUNTER-STATEMENT OF FACTS

Defendants do not dispute Plaintiff was injured in 1996, and has experienced a complicated medical history since that time. Defendants deny Plaintiff's conditions were caused by Children's Motrin or any conduct of Defendants. Defendants also state the Children's Motrin label gave adequate warnings, and that a different warning would not have prevented Kiley Wolfe from using the medication. Defendants deny any wrongdoing.

Plaintiff cannot prove Children's Motrin Children's Motrin can cause SJS and VBDS at all. Nor can Plaintiff prove Children's Motrin caused her SJS and VBDS in this case. Even if it had, Plaintiff must also prove that a different warning would have prevented her injuries and she cannot prove that a different warning would have changed Plaintiff's mother's conduct in May and June 1996. The evidence will show that, among other things, (1) Plaintiff's mother read only the dosing information — not the warnings — when first giving Children's Motrin to Plaintiff; (2) she continued administering Children's Motrin to Plaintiff upon her doctor's advice, after she allegedly studied the box and bottle that warned of the seriousness of the very symptoms Plaintiff was experiencing; (3) she had previously given Aleve to Plaintiff without reading the warning label on the product; (4) she gives Children's Motrin to her young sons even after Plaintiff's alleged reaction; and (5) she still uses ibuprofen herself. A different warning on

the Children's Motrin would not have stopped Plaintiff's mother from giving her the Children's Motrin.

Plaintiff cannot prove she is entitled to punitive damages. Plaintiff must prove by clear and convincing evidence that Defendants acted with malice in providing the allegedly inadequate warning. Malice exists only where a defendant's conduct is motivated by ill will toward the plaintiff or where deliberate conduct by the defendant is so outrageous that it shows malice toward the plaintiff. Plaintiff cannot prove either of these elements by clear and convincing evidence. There is no evidence that Defendants' conduct toward Plaintiff was either malicious or outrageous. McNeil sold Children's Motrin with an FDA-approved warning. In 1984, the FDA reviewed and approved the first new drug application for OTC ibuprofen use for pain relief and fever reduction in adults. In so doing, the FDA determined that OTC ibuprofen was "safe and effective" for those purposes when used in compliance with the approved labeling. Since the FDA's initial approval of adult OTC ibuprofen in 1984, the FDA has reviewed and approved numerous additional ibuprofen products for OTC use, including a pediatric formulation in 1995. In all of these cases, the FDA approved the products as "safe and effective" for OTC use when used in accordance with their approved labeling.

As to risks of SJS, (1) notwithstanding reports of temporal association between use of ibuprofen and SJS, there is a scientific question of whether Children's Motrin can cause SJS at all, and the most recent, robust epidemiological study reported no statistically significant risk of SJS from use of ibuprofen, and the authors of that study concluded ibuprofen is a drug of common usage probably not associated with SJS[1]; (2) McNeil submitted accurate information to

[1] Maja Mockenhaupt, *et al.*, *Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risks with Emphasis on Recently Marketed Drugs*, 128 J. Investigative Dermatology 35-44 (2008).

the FDA regarding risks of use of Children's Motrin from the Boston University Fever Study; and, (3) after thorough review of the risks of SJS, the FDA determined that Children's Motrin was safe for OTC use and that OTC ibuprofen labels should not include an SJS warning.

Plaintiffs distort Dr. Temple's testimony concerning the 1996 label in claiming "McNeil has admitted the 1996 Children's Motrin label should have included instructions to "stop use" if new symptoms appear. In fact, Dr. Temple testified "I like the language. I think the label back then was adequate." Finally, the FDA recommendation in 2005 that McNeil (and other manufacturers of OTC ibuprofen products) add the terms "skin reddening", "rash" and "blisters" to its OTC Motrin label is not a finding that the label in 1996 was inadequate.

III. DEFENDANTS' LIST OF TRIAL WITNESSES

Subject to the reservation of rights stated therein and below, Defendants' trial witness list, other than impeachment witnesses, is attached hereto as Exhibit A. The listing of witnesses does not represent a certification of their availability, or control by Defendants.

Defendants reserve the right to supplement or amend their witness list based upon any decisions by the Court that affect the scope of evidence in this trial or any change to Plaintiff's witness list. Defendants reserve the right to withdraw any witness. Defendants also reserve the right to call, live or by deposition, any witness (i) identified by the opposing party, (ii) for which the opposing party designates deposition testimony, (iii) who is identified hereafter in discovery, or (iv) consistent with their rights under the Federal Rules of Evidence. By identifying these witnesses, Defendants do not intend to waive any of their objections to testimony, exhibits, or other evidence or argument.

Defendants anticipate eliciting testimony from Johnson & Johnson, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., and/or McNEIL-PPC, Inc. employees and/or advisors, who do not regularly give expert testimony, related to, or arising from, their professional activities and/or areas

of responsibility – whether direct or supervisory. This testimony may include information of a medical, scientific, or otherwise technical nature related to their area of professional expertise or skill. It may include factual as well as opinion testimony as categorized by the federal rules of evidence.

The listing of witnesses in Defendants' witness list does not represent a certification of their availability or being under Defendants' control.

IV. DEFENDANTS' SCHEDULE OF TRIAL EXHIBITS

Subject to the reservation of rights stated therein and below, Defendants' list of trial exhibits, other than impeachment exhibits, is attached hereto as Exhibit B.

Defendants submit their list of pre-marked exhibits to be used in whole or in part. Defendants reserve their rights to use as exhibits all documents identified by Plaintiff as trial exhibits. Defendants additionally reserve all rights to supplement their exhibit list as may be warranted during the course of trial. In identifying documents, Defendants do not admit that all or part of any document is admissible at trial, or may be used in any way. Defendants reserve all rights to object to use of all or any part of any document listed as a trial exhibit.

V. OBJECTIONS TO ADMISSIBILITY OF EVIDENCE

Pursuant to the Court's Pretrial Procedure for Civil cases, Defendants submit the following potential objections to (a) the admissibility of any exhibit based on authenticity; (b) the admissibility for any reason (except relevancy) of any evidence expected to be offered; and, (c) the admissibility of any opinion testimony from lay witnesses pursuant to Federal Rule of Evidence 701. Defendants investigation is continuing, and their trial preparation is not complete. Defendants identify the following potential objections to evidence without waiver of their right to modify or supplement objections herein, and/or object further. Defendants will file motions in limine pursuant to the scheduling order in this case, and reserve the right to supplement their objections and submit other objections as appropriate.

Defendants' objections to Plaintiff's list of trial exhibits requiring authenticity, are attached hereto as Exhibit C.

Defendants would object to the admissibility of the following evidence expected to be offered at trial:

Evidence of or Reference to Adverse Event Reports. Defendants may seek an order to exclude evidence of or reference to adverse event reports ("AERs") submitted to the FDA regarding persons who may have developed SJS/TEN or other skin conditions, or VBDS, after using ibuprofen or other non-steroidal anti-inflammatory drugs on the grounds that evidence of, or reference to, AERs should be excluded because such evidence is inadmissible hearsay. Furthermore, such evidence would be unfairly prejudicial to the Defendants because it may cause the jury to improperly infer that ibuprofen caused the reported adverse events and that Motrin can cause SJS/TEN, and/or VBDS. In addition, such evidence or references are not relevant to this case because neither the FDA nor the judiciary considers AERs reliable proof of causation.

Evidence of Adverse Drug Reaction Data Listings from WHO. Defendants may seek an order to exclude evidence of or reference to data listings of adverse event reports from the WHO's Adverse Drug Reaction ("ADR") Database, including reports of SJS, TEN, and other skin conditions, or VBDS, on the grounds that the WHO ADR database consists of summaries of intermittent *suspected* reports of adverse drug reactions. This data does not establish a relationship between a patient's symptoms and ibuprofen. WHO data includes duplicative entries and entries cumulative of those in the FDA database. The WHO's ADR listings are also irrelevant and inadmissible because they have no bearing on issues of causation or any other issue in this case.

Evidence of SJS References in the BUFS Data. Defendants may seek an order to exclude evidence of the two references to SJS found in certain data from the Boston University Fever Study ("BUFS") on the grounds that the two SJS references in the BUFS data are inadmissible hearsay and do not evidence cases of SJS associated with ibuprofen. In addition, evidence of the two SJS references in the BUFS data should be excluded on the grounds that the references cannot be properly authenticated, and will be unduly prejudicial, will waste time, and will confuse the jury. Evidence of SJS references in the BUFS Data is also not relevant to the issues in this case.

Evidence that the OTC Motrin Label Should Have Contained Warnings Rejected By the FDA. Defendants may seek an order to exclude evidence or arguments that the OTC Children's Motrin label should have included warnings that have been rejected by the FDA, e.g., "SJS", "TEN", "life-threatening reaction," or "stop use" on the grounds that such evidence is preempted, unduly prejudicial, would mislead the jury, and result in undue consumption of time. Such evidence or arguments may mislead the jury into believing that such warnings could have, and should have, been added to the labeling had there been no regulatory involvement. In addition, permitting Plaintiff to introduce testimony that the OTC Motrin label should have warned of SJS, TEN, "life-threatening" consequences, or to "stop use and get emergency medical help immediately" will cause undue delay because Defendants would be required to rebut Plaintiff's misleading arguments by offering evidence to explain FDA regulations, agency directives regarding the content and appearance of OTC labeling, and the determination and implications of having a product "misbranded." Testimony that the OTC Children's Motrin label should have included warnings rejected by the FDA is also irrelevant.

The 2005 Citizen's Petition. Defendants may seek an order to exclude evidence of or arguments regarding a Citizen's Petition submitted to the FDA in 2005 by a group of plaintiffs' experts and plaintiffs, making claims similar to those in this action. Most of those claims were rejected by the FDA. The 2005 Citizen's Petition contains inadmissible hearsay and any probative value of the petition is outweighed by its prejudicial effects. The 2005 Citizen's Petition is an out-of-court statement that would be offered to prove the truth of matters asserted. In fact, the Citizen's Petition contains multiple levels of hearsay because it contains various statements from individuals other than the authors of the Petition. Moreover, the Citizen's Petition lacks circumstantial guarantees of trustworthiness necessary for an exception to the hearsay rule. The individuals who prepared and submitted the Citizen's Petition are experts hired by plaintiffs in various lawsuits alleging that Motrin caused SJS or TEN, including experts serving on Plaintiff's behalf in this case.

In addition, the 2005 Citizen's Petition will confuse and mislead the jurors, and prejudice Defendants. The jury may view the 2005 Citizen's Petition as an impartial attempt by concerned healthcare providers to have the label of Motrin changed to include warnings about SJS and TEN when in fact it was brought by individuals who were retained as experts by plaintiffs in various lawsuits involving claims that Motrin caused SJS and TEN. Moreover, admitting the 2005 Citizen's Petition will cause an undue delay and waste of judicial resources. Defendants will be forced to present documentary evidence and expert evidence designed to explain the citizen's petition process, who submitted the 2005 Citizen's Petition to the FDA, and why the information contained in the Petition is unreliable and speculative.

Evidence of McNeil's 1984 Petition and Subsequent Petition for Reconsideration. Defendants may seek an order to exclude evidence of or arguments regarding McNeil's 1984

petition and subsequent petition for reconsideration on the grounds that evidence or arguments regarding the petitions is unduly prejudicial, misleading and confusing, and would require undue consumption of time. In addition, such evidence is irrelevant. The petitions do not involve SJS or TEN and, therefore, would neither prove nor disprove any fact of consequence to this case, Finally, the petitions were submitted over 20 years before Plaintiff used Motrin and they address the FDA's safety comparison of ibuprofen and acetaminophen under different regulatory guidelines.

Evidence of Foreign Labeling and Regulatory Actions. Defendants may seek an order to restrict evidence of or arguments regarding foreign ibuprofen products, their labels, and any foreign regulatory actions regarding the same on the grounds that evidence of foreign labeling will cause unfair prejudice, jury confusion, and undue delay (*i.e.*, if Plaintiff were permitted to offer evidence of foreign labels "stronger" than the US label, Defendants should be able to offer evidence of different regulatory schemes and regulations in the US, and of "weaker" foreign labels — the result would be confusion and waste of time). In addition such evidence is irrelevant and inadmissible because the FDA regulates labeling for Motrin under US law which sets forth a comprehensive scheme designed to ensure the safety and efficacy of drugs in the United States. Foreign regulatory actions are driven by different laws and factors arising from each country's unique political, social and economic situation. Because of these differences, evidence of foreign regulatory schemes and actions does not inform a jury of relevant issues regarding drugs approved by the FDA. Because the Motrin product at issue in the case was marketed and sold in accordance with FDA regulations, foreign regulatory standards are irrelevant and thus should be excluded.

Inadmissible Hearsay Statements Made by FDA Employees Regarding Children's Motrin and/or Motrin. Defendants may seek an order to restrict evidence of statements made by employees of the FDA Division of Drug Marketing, Advertising and Communications after reviewing McNeil's draft proposed advertising and promotional materials for compliance with FDA requirements ("informal FDA letters") on the grounds that such evidence is inadmissible hearsay. In addition, such evidence should be excluded on the grounds that it would cause unfair prejudice to Defendants, jury confusion and undue delay because the jury likely will not appreciate the important difference between the position of an employee of the FDA and a final and official determination of the FDA.

Documents and Testimony Concerning Alleged Inadequacy of FDA's Drug Safety Monitoring. Defendants may seek an order precluding Plaintiff from introducing reports from government agencies or journal articles that suggest the FDA cannot effectively monitor drug safety and from eliciting testimony from witnesses concerning such allegations on the grounds that such documents and testimony are inadmissible hearsay and do not qualify under any hearsay exception including the exceptions for official records and business records. These documents do not evidence anything related to FDA approvals of the product at issue in this action. In addition, such documents and testimony would cause unfair prejudice to Defendants, jury confusion, and undue delay, and are irrelevant.

Marketing and/or Promotional Materials Related to Motrin Not Reviewed and Relied Upon By Plaintiff. Defendants may seek an order excluding any evidence regarding Motrin marketing and/or promotional materials that were not reviewed and relied upon by Plaintiff or her mother, who purchased the product at issue, on the grounds that such evidence is prejudicial, confusing and wasteful of time, and irrelevant.

Evidence of Other Lawsuits, Claims or Settlements Involving Motrin or Other Ibuprofen Products. Defendants may seek an order excluding evidence or arguments regarding other lawsuits, claims or settlements regarding persons not parties to this case who allegedly experienced adverse reactions from ingesting Motrin and/or other ibuprofen products on the grounds that such evidence is inadmissible hearsay. Evidence of other lawsuits and claims are out-of-court statements which would be offered to prove the truth of the matter asserted. In addition, other lawsuits, claims or settlements cannot be authenticated and such evidence would cause unfair prejudice, jury confusion, and undue delay as it would necessitate "mini-trials" to determine the facts in each such matter as a predicate to potential relevance. The medical causation issues in each of these cases are uniquely based on the particular medical history of the person and other facts.

Testimony or Questions Regarding Rechallenges Occurring in Upjohn Clinical Trials. Defendants may seek an order precluding Plaintiff from introducing evidence, eliciting testimony, or questioning witnesses regarding alleged rechallenges to unidentified ibuprofen-containing products in clinical studies conducted by the Upjohn Company on the grounds that such evidence is inadmissible hearsay because Plaintiff would attempt to offer testimony regarding the alleged rechallenges for the truth of the matter asserted. In addition, reports of claimed rechallenges in Upjohn Studies cannot be properly authenticated, reference to such studies will cause unfair prejudice, jury confusion, and undue delay. Any such evidence is also irrelevant.

Evidence of or Reference to McNeil's 2009 and 2010 Voluntary Recalls of Certain Motrin Products. Defendants may seek an order excluding evidence of or reference to voluntary recalls of certain pharmaceutical products, including certain Motrin products, by

McNeil in 2009 and 2010 on the grounds that such evidence or references would unfairly prejudice Defendants, confuse the jury, require undue consumption of time, and is irrelevant. The recalls related to manufacturing quality control issues having no connection to the product at issue or injuries alleged in this action.

Evidence of or Reference to Drugs Withdrawn/Removed from Market. Defendants may seek an order to exclude evidence of or reference to non-Motrin drugs being withdrawn or removed from the market on the grounds that such evidence would result in unfair prejudice, confusion of the issues, and undue delay. It is also irrelevant.

Expert Testimony. Defendants may seek an order to preclude testimony regarding the results of an "LTA" test performed by Plaintiff's expert Dr. Neuman, on the basis that it is not generally accepted by the scientific community as reliable, has not been shown to be reliable as applied to Plaintiff, and is based on data Dr. Neuman has refused to disclose in prior depositions.[2]

Defendants expect to object to testimony of Plaintiff's experts, including to testimony that is cumulative, consists of legal conclusions, expresses, or is based on, subjective opinions and views of corporate ethics or conduct, exceeds their expertise and/or qualifications, is unreliable, consists of personal opinions, or is not based on reliable methodology.

Pursuant to Federal Rule of Evidence 701, Defendants would object to the admissibility of opinion testimony offered by Plaintiff that is not: (a) rationally based on the perception of the witness; (b) helpful to a clear understanding of the witnesses' testimony or

[2] Due to scheduling conflicts and other reasons, Dr. Neuman has not yet been deposed in this case; nor have several other experts.

determination of a fact in issue; and (c) based on scientific, technical, or other specialized knowledge.

Such opinion testimony may include, for example, testimony by Plaintiff's father, William Wolfe, a lawyer, expert or company witnesses concerning legal conclusions such as Defendants' legal liability or compliance with FDA regulations and reporting requirements. Defendants would further object pursuant to Federal Rule of Evidence 701 to opinion testimony by Plaintiff's treating physicians or other unqualified witnesses that ibuprofen can cause SJS/TEN and/or VBDS and did cause Plaintiff to experience these conditions, that the label of the OTC Motrin given to Plaintiff did not adequately warn of risks of use, or that Defendants engaged in malicious conduct sufficient to entitle Plaintiff to an award of punitive damages.

VI. ESTIMATED TRIAL TIME

Defendants estimate that the trial of this matter will take 20 court days to complete.

The case will be tried to a jury.

VII. SPECIAL COMMENTS

A. Defendants State The Following Issues of Law Remain For Determination

1. Whether any Defendant owed Plaintiff a duty to provide different warnings.

2. Whether any Defendant failed to provide reasonable warnings.

3. Whether a causal connection exists between any alleged failure to warn and the injuries Plaintiff contends resulted from use of Children's Motrin.

4. Whether Plaintiff experienced injury because the warnings at issue were defective and unreasonably dangerous.

5. Whether Plaintiff has suffered damages caused by her use of Children's Motrin and, if so, in what amount.

B. Defendants' Statement of Issues of Fact Which Remain to Be Litigated

1. Whether Children's Motrin can cause the injuries alleged.

2. Whether Children's Motrin did cause the injuries alleged.

3. Whether there is a causal connection between the warnings on the Children's Motrin used by Plaintiff and the injuries alleged.

4. The nature and extent of injuries allegedly caused by Plaintiff's use of Children's Motrin, if any.

5. The extent of damages allegedly caused by Plaintiff's use of Children's Motrin, if any.

6. Whether Johnson & Johnson is liable for any actions by McNEIL-PPC, Inc. or any division that is a party to this case.

7. Whether Johnson & Johnson Pharmaceutical Research and Development, L.L.C. is liable for any tort committed by McNEIL-PPC, Inc. or any division that is a party to this case.

C. Defendants do not contest the following facts, but reserve the right to present evidence on these facts at trial:

1. Defendant Johnson & Johnson is a New Jersey Corporation.

2. Defendant McNEIL-PPC, Inc. is a New Jersey corporation. McNEIL-PPC, Inc. is an indirect subsidiary of Johnson & Johnson.

3. Defendant McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is an unincorporated division of McNEIL-PPC, Inc.

4. McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. manufactures and markets Children's Motrin.

5. McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., or its predecessor, McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC, Inc., is and was, at all

material times hereto, in the business of manufacturing and marketing a product called Children's Motrin.

6. McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is in the business of manufacturing and selling Children's Motrin to users throughout the United States through various entities and retailers, including but not limited to pharmacies.

7. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. is a New Jersey limited liability company. Johnson & Johnson Pharmaceutical Research & Development, L.L.C. is an indirect subsidiary of Johnson & Johnson.

8. Plaintiff Kiley Wolfe is a citizen of Louisiana.

9. The amount in controversy exceeds $75,000.00.

Respectfully submitted,

Dated: July 22, 2011

/s/ David F. Abernethy
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CERTIFICATE OF SERVICE

I, Kadene K. Chin, hereby certify that on this date, the foregoing document was served on the following counsel via the Court's electronic case filing system with a courtesy copy to follow via regular mail:

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